



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF  
CHEMICAL SAFETY AND  
POLLUTION PREVENTION

**MEMORANDUM**

Date: April 4, 2017

Subject: Follow-up to Protocol Review for Ottoman  
Protocol File Symbol 777-PA3 (DP #429159)

From: Alison Clune  
Efficacy Evaluation Team  
Product Science Branch  
Antimicrobials Division (7510P)

Thru: Mark Perry, Team Leader  
Product Science Branch  
Antimicrobials Division (7510P)

To: Eric Miederhoff, PM 31  
Regulatory Management Branch I  
Antimicrobials Division (7510P)

Applicant: Reckitt Benckiser, LLC  
399 Interpace Parkway  
Parsippany, NJ 07054

Agent: Rhonda Jones  
Scientific and Regulatory Consultants, Inc.  
201 W. Van Buren St.  
Columbia City, IN 46725

A handwritten signature in blue ink, appearing to read "Alison Clune", is located to the right of the "From:" field.

A handwritten signature in black ink, appearing to read "Mark Perry", is located to the right of the "Thru:" field.

**Formulation from the Label: No formulation detailed on the proposed label. Protocol intended to be used for multiple products.**

**I BACKGROUND**

The subject protocol was submitted to support disinfection (bactericidal, fungicidal) claims on porous soft surfaces. The attached revised protocol was submitted in response to the Efficacy Protocol Review dated September 25, 2015. As stated in the agent's email to Eric Miederhoff and John Cowden dated September 29, 2015, the revised protocol includes changes consistent with the recommendations in the previous Protocol Review.

The revised protocol, dated September 29, 2015, is attached to this review.

## II AGENCY COMMENTS TO PROTOCOL REVISIONS

1. Agency's Initial Response: The Assay Acceptance Criteria and Retesting Guidance should follow the AOAC Germicidal Spray Test and/or OCSPP 810.2200 criteria for *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Trichophyton mentagrophytes*, and additional organisms. The stated acceptable mean log<sub>10</sub> density between 4.0 and 5.5 log/carrier should only apply to *Salmonella enterica*. For *Staphylococcus aureus* and *Pseudomonas aeruginosa*, the acceptable mean log<sub>10</sub> density should be between 5.0 and 6.5 log/carrier. For *Trichophyton mentagrophytes*, the acceptable mean log<sub>10</sub> density should be between 4.0 and 5.0 log/carrier. For additional organisms, the acceptable mean log<sub>10</sub> density should be at least 4.0 log/carrier.  
Registrant's Response: The Assay Acceptance Criteria and Retesting Guidance were revised to reflect the above criteria.  
Agency's Final Response: The proposed changes are acceptable.
2. Agency's Initial Response: In the section "Test System Preparation (Culture Transfer)", step 1 should indicate that in the final subculture step for bacteria 10 µL of the 24 hour culture should be transferred to the tubes containing 10 mL broth.  
Registrant's Response: The 24-hour culture volume unit was corrected.  
Agency's Final Response: The proposed changes are acceptable.